DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 8, 2014

Innovative Neurotronics, Inc.
c/o Mr. Glen Neally
3600 North Capital of Texas Highway
Building B, Suite 150
Austin, Texas 78746

Re: K140886
Trade Name: WalkAide System
Regulation Number: 21 CFR 882.5810
Regulation Name: External functional neuromuscular stimulator
Regulatory Class: Class II
Product Code: GZI
Dated: May 5, 2014
Received: May 13, 2014

Dear Mr. Neally:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140886

Device Name
WalkAide System

Indications for Use *(Describe)*
The Innovative Neurotronics WalkAide External Functional Neuromuscular Stimulator (WalkAide System) is intended to address the lack of ankle dorsiflexion in patients who have sustained damage to upper motor neurons or pathways to the spinal cord. During the swing phase of gait, the WalkAide System electrically stimulates the appropriate muscles that cause ankle dorsiflexion and may thus improve the gait in patients with chronic stroke. Medical benefits of Functional Electrical Stimulation (FES) may include prevention/ retardation of disuse atrophy, increased local blood flow, muscle re-education, and maintained or increased joint range of motion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary
for the
Innovative Neurotronics, Inc.
WalkAide System

1. SPONSOR

Innovative Neurotronics, Inc.
3600 N. Capital of Texas Highway
Bldg. B, Suite 150
Austin, Texas 87846

Contact Person: Glen Neally – Director of Quality and Regulatory
Telephone: 1-512-721-1903
Fax 1-512-721-1939

Date Prepared: May 5, 2014

2. DEVICE NAME

Proprietary Name:	WalkAide
Common/Usual Name:	External Neuromuscular Functional Stimulator
Classification Names:	External Neuromuscular Functional Stimulator
Classification Number:	21 CFR 882.5810
Product Code:	GZI

3. PREDICATE DEVICES

WalkAide System– K123972

4. INTENDED USE

The Innovative Neurotronics WalkAide External Functional Neuromuscular Stimulator (WalkAide System) is intended to address the lack of ankle dorsiflexion in patients who have sustained damage to upper motor neurons or pathways to the spinal cord. During the swing phase of gait, the WalkAide System electrically stimulates the appropriate muscles that cause ankle dorsiflexion and may thus improve the gait in patients with chronic stroke. Medical benefits of Functional Electrical Stimulation (FES) may include prevention/ retardation of disuse atrophy, increased local blood flow, muscle re-education, and maintained or increased joint range of motion.

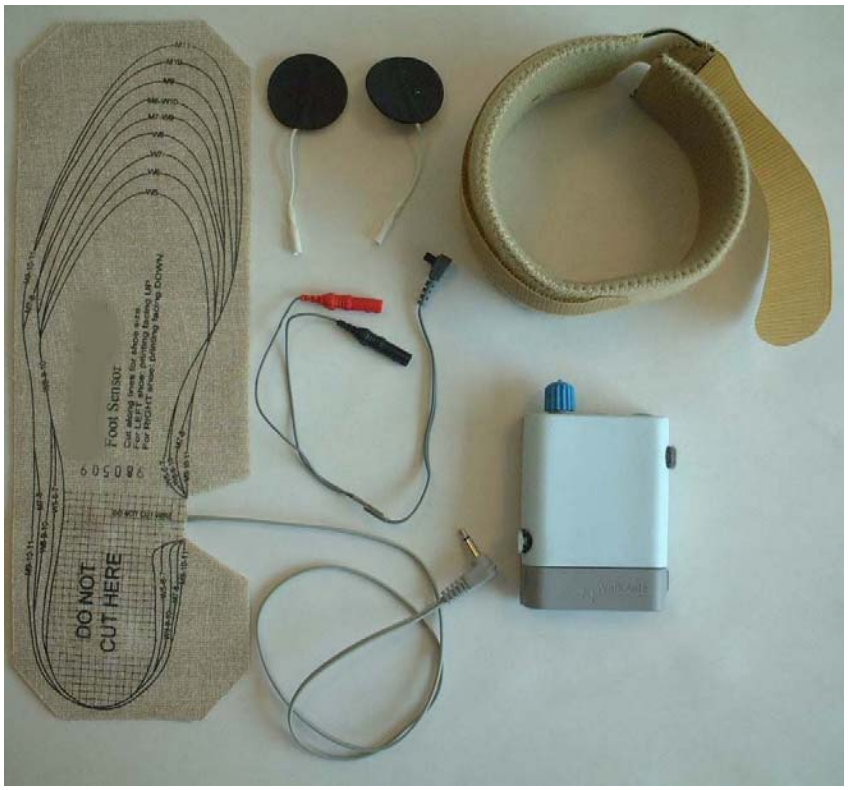
5. DEVICE DESCRIPTION

The WalkAide is an external functional electrical stimulator. It is a small device that attaches to the leg just below the knee, near the head of the fibula. During a gait cycle, the WalkAide stimulates the common peroneal nerve, which innervates the tibialis anterior and other muscles that cause dorsiflexion of the ankle. The WalkAide System consists of the WalkAide Patient Kit and the WalkAide Clinician Kit . The WalkAide Patient Kit comprises of all the components and accessories that the patient will take home and use. The Clinician System comprises the accessories that a clinician (i.e., orthotic specialist, physiotherapist, occupational therapist, etc.) will use to set up a patient's WalkAide.

WalkAide Patient Kit

The WalkAide Patient Kit consists of the components and accessories that the patient takes home. The WalkAide Patient Kit includes (See Fig 4.1):

- WalkAide Control Module (Stimulator Unit)
- WalkAide Leg Cuff
- WalkAide Electrode Cable
- Electrodes (ordered seperately)
- Foot Sensor (Optional)



WalkAide Patient Kit

WalkAide Control Module (WalkAide)

As with the parent K123972 WalkAide control module, the Innovative Neurotronics WalkAide Control Module houses the electronics and controls of the WalkAide system, and delivers electrical stimulation to the end-user's peroneal nerve via surface electrodes. The WalkAide attaches to the Leg Cuff and provides the stimulation pulse to the electrodes. The WalkAide requires a single AA battery to operate.

WalkAide attached to WalkAide Cuff on a Patient's Leg

As with the K123972 WalkAide, the Innovative Neurotronics WalkAide is a microprocessor controlled device, and uses an EEPROM to store device, user, and configuration information. The intensity is controlled by the potentiometer on the top face of the WalkAide control module. The position of the potentiometer controls the appropriate stimulation intensity.

Stimulation could be triggered by three mechanisms: the Tilt Sensor inside the control module, a Foot Sensor or Heel Sensor, or through the Hand Switch (the WalkLink.) Three LEDs (green, amber, and red) provide indications such as start up, stimulation, low battery, and fault. Additional information about these indicators is provided in the User Manual in Appendix A-2.

WalkAide Bi-Flex Cuff

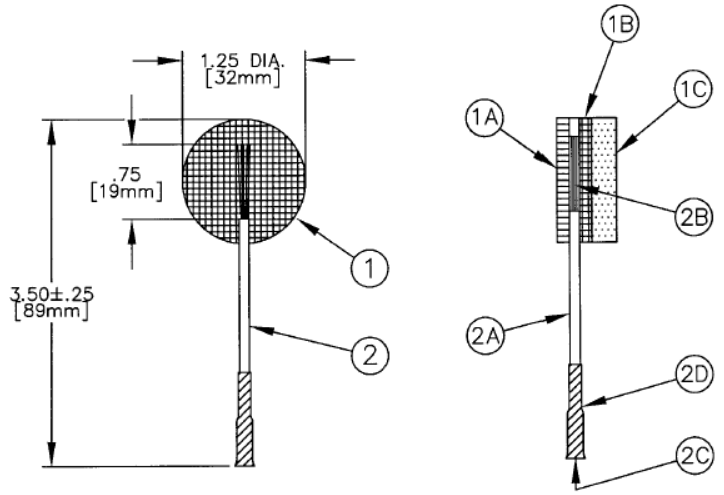
The WalkAide is designed for single-handed application and removal. It may take a bit of practice to develop a routine that works best for each person. The WalkAide is applied directly to the leg and can be easily worn under most clothing. The clinician will find the optimal placement of the electrodes on the initial visit. The electrode placement will be marked on

the inside of the cuff via Red and Black Electrode Locators and the position should not be moved by the patient.

WalkAide Cuff

Electrodes

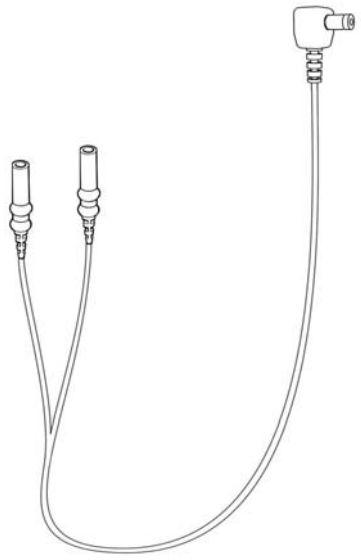
As with the K123972 Walk-Aide, the Innovative Neurotronics WalkAide System uses two surface electrodes. The WalkAide electrodes consist of electrodes that have been cleared under 510(k) (currently numbers K872976, K962332, K070807).



WalkAide Electrodes

Electrode Cable

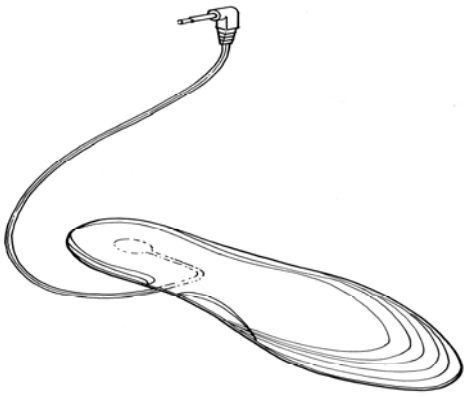
This is a Y connector cable for connecting the electrodes with WalkAide. One end is connected to the connector slot on the back of the electrode, and the other two ends (black and red) are connected to respective electrodes.



WalkAide Electrode Cable

Foot Sensor (Optional Item)

The Foot Sensor is the same as in the parent WalkAide system. No changes have been made to the foot sensor. The Foot Sensor is designed for those individuals whose leg movement is limited such that the Tilt Sensor cannot be adequately used. The Foot Sensor is based on a force sensor resistor (FSR) as the detection element. The Foot Sensor plugs into the receptacle on the side of the WalkAide control module as it did in the parent device.



Foot Sensor

WalkAide Clinician Kit

The WalkAide Clinician Kit, which is similar to the Clinician System used in the parent WalkAide, is used by trained professionals (*clinicians*) in a clinical setting to configure WalkAide for an individual user. The WalkAide Clinician Kit is only used by the clinician and it is not sent with the patient.

Innovative Neurotronics uses the WalkAide Clinician System Software called the WalkAnalyst, with Notebook/Tablet PC/Desktop platform for the ease of use and better display. The Notebook/Tablet PC/Desktop is not provided by Innovative Neurotronics. The WalkAnalyst has been developed and validated according to regulatory guidance documents.

The WalkAide consists of the following components:

- WalkAnalyst Software
- WalkLink (Hand Switch)
- Heel Sensor

Clinician Kit without WalkAnalyst Software

WalkAnalyst Software

The WalkAnalyst software has been developed exclusively for the proposed Innovative Neurotronics WalkAide. This software can be installed on a Tablet PC, notebook, or desktop PC hardware platform. The WalkAnalyst performs the following functions:

- Set up configuration of WalkAide Control Module, which includes management of data input from tilt sensor, and heel/foot sensor
- Management of patient information
- Graphical display of stimulation information and gait recordings
- Analysis of data and optimization of stimulation parameters
- Report generation

The WalkAnalyst software communicates with WalkAide via a Bluetooth wireless communication device in the WalkLink.

WalkLink (Hand Switch)

The WalkLink is only used during the patient set-up and control module configuration process. The WalkLink serves two purposes (1) the

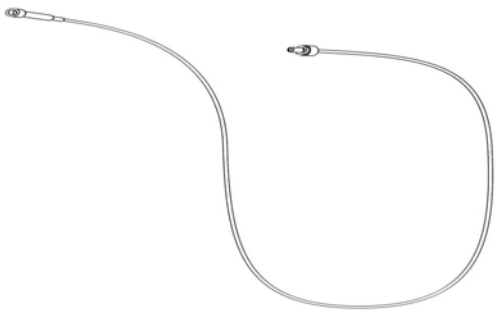
Clinician can stimulate the patient at the appropriate times during the set-up process (2) It communicate gait recording from WalkAide to the PC (Tablet/Notebook/Desktop) using Bluetooth (BT) wireless communication protocol. It should be noted that WalkAide itself does not have Bluetooth functionalities. WalkAide communicates with WalkLink using the WalkLink cable. WalkLink transmits the information received from WalkAide to the PC using the Bluetooth protocol.

The WalkLink contains a stimulation button and three LED indicators. The green blinking indicator shows adequate battery voltage, the red indicator indicates low battery or error, and the blue blinking indicator indicates that BT link is established.

WalkLink

WalkLink Cable

The WalkLink cable connects WalkLink with WalkAide. This cable contains standard RS232 communication lines. This is a 5 conductor stranded cable approximately 40 inches long cable.



WalkAide to WalkLink Cable

Heel Sensor

The heel sensor is the same patient heel sensor used in the parent WalkAide system. No changes have been made to the Heel Sensor. The design is similar to the Foot Sensor, as it incorporates a force sensitive sensor (FSR) as the detection element. The Heel Sensor is intended for use in the clinic by the Clinician during the device set-up stage.

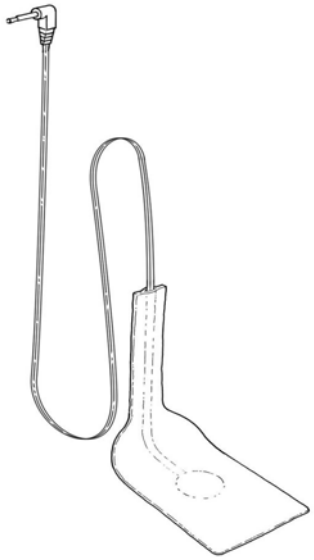


Fig 4.10: Heel Sensor

4.5 Operations and Set-up of the WalkAide System

The operation and set-up of the WalkAide system is detailed in the Clinician Manual. The following is a summary:

The patient places the back electrode slightly posterior and distal to the head of the fibula and the front electrode on the upper 1/3 of the tibialis anterior muscle over the muscle belly. The back electrode is connected to the black lead and the front electrode to the red lead. The WalkAide is turned on by rotating the intensity control on the Control Module. The round intensity knob is moved counter-clockwise through "0" or in the direction of increasing numbers. The STIM button labeled (⎍) is depressed for 1 to 2 seconds to provide a test stimulus. An amber light on the top of the

WalkAide Control Module indicates that the unit is stimulating. If the ankle movement produced by the stimulus is too small, the intensity control is turned up or the black electrode is adjusted slightly to the rear, then application of the test stimulus is attempted again. Stimulation consists of delivering a train of biphasic current pulses to the common peroneal nerve via two surface electrodes. The goal is to produce a relatively pure dorsiflexion of the ankle with as low stimulus intensity as possible. Once the optimal electrode positions have been found, the cuff is placed over the electrodes.

The cuff is then removed with the electrodes that are affixed by Velcro to the inside of the cuff. The Clinician then positions the electrodes on the leg cuff for patient reference during future electrode replacement. The leads from the electrodes are threaded through the holes on the cuff. The black lead of the Y-connector cable is connected to the back electrode and the red to the anterior electrode. The electrodes, leads and connectors are placed in the groove or pocket of the cuff and covered with a Velcro strap. A heel sensor is placed in the patient's shoe on the affected side and is connected to the WalkAide Control Module. As with the parent Walk-Aide, the WalkAide Control Module houses the electronics and controls of the WalkAide, and delivers electrical stimulation to the patient via two surface electrodes.

The Clinician collects and analysis gait recording by using WalkAnalyst Software and according to set-up shown in Fig 4.11. After optimal parameters are selected, WalkAide is configured using the selected parameters.

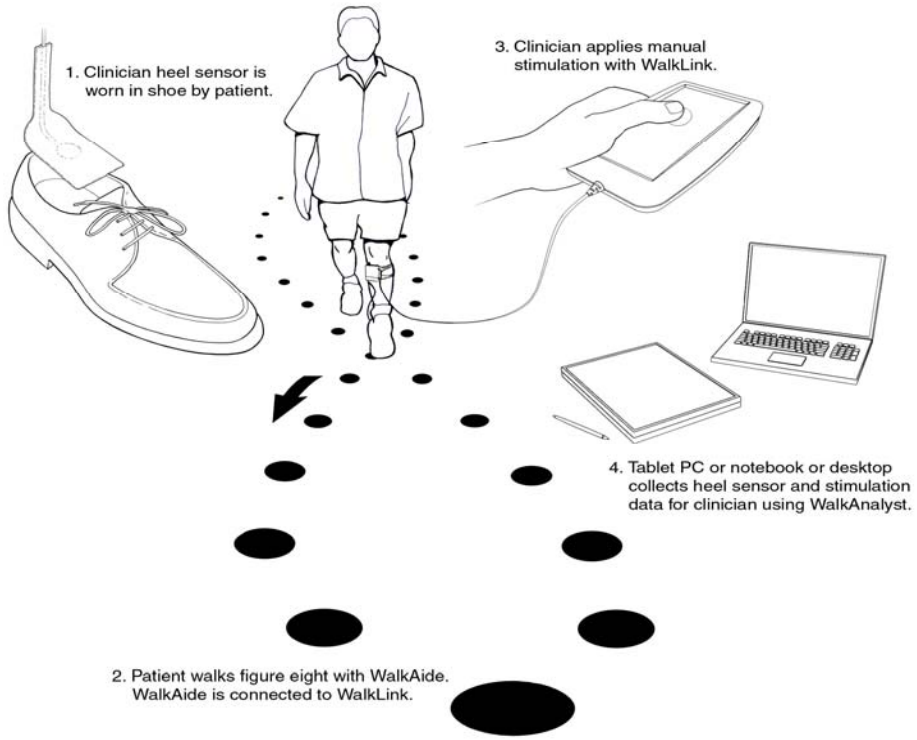


Fig 4.11: WalkAide Set-up Process

Once set up and configuration has been completed by the Clinician, WalkLink is disconnected from the WalkAide. WalkAide, including the accessories such as the WalkAide Cuff, Electrodes, Electrode Cable, and Foot Sensor (optional item) is provided to the patient.

WalkAide in normal operation mode will use the Tilt Sensor or optional Foot Sensor to sense the appropriate point in the patient's gait (walk) cycle to trigger stimulation. The WalkAide provides visual and audible indications for various conditions such as operational status and low battery condition.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The purpose of this 510(k) is to update the submission of the Walk-Aide System (K123972) to include in the Indications For Use Summary Statement the specific population of chronic stroke patients for the specific indication of improved gait. **This is the only change in this submission.**

Clinical data is submitted to support the difference in indication for use. The randomized controlled trial utilized an un-blinded, parallel group design. The purpose of this study was to compare the performance of the WalkAide Functional Electrical Stimulation device (WA) versus an Ankle-Foot Orthosis (AFO) in subjects with chronic stroke. Subjects were required to be at least 6 months post stroke. The study data was analyzed using an intention to treat analysis with missing data points calculated using multiple imputations. **The clinical trial data outcomes support chronic stroke population for gait improvement.**

Comparison Conclusion Table:

FEATURE	INNOVATIVE NEUROTRONICS, INC. WALKAIDE Current Submission	INNOVATIVE NEUROTRONICS, INC. WALKAIDE K123972	COMPARISON
Intended Use	**SUMMARY STATEMENT** The Innovative Neurotronics WalkAide External Functional Neuromuscular Stimulator (WalkAide System) is intended to address the lack of ankle dorsiflexion in patients who have sustained damage to upper motor neurons or pathways to the spinal cord. During the swing phase of gait, the WalkAide System electrically stimulates the appropriate muscles that cause ankle dorsiflexion and may thus improve the gait in patients with chronic stroke. Medical benefits of Functional Electrical Stimulation (FES) may include prevention/ retardation of disuse atrophy, increased local blood flow, muscle re-education, and maintained or increased joint range of motion.	**SUMMARY STATEMENT** The Innovative Neurotronics WalkAide External Functional Neuromuscular Stimulator (WalkAide System) is intended to address the lack of ankle dorsiflexion in patients who have sustained damage to upper motor neurons or pathways to the spinal cord. During the swing phase of gait, the WalkAide System electrically stimulates the appropriate muscles that cause ankle dorsiflexion and may thus improve the patient's gait. Medical benefits of Functional Electrical Stimulation (FES) may include prevention/ retardation of disuse atrophy, increased local blood flow, muscle re-education, and maintained or increased joint range of motion.	This current submission has included the indication of gait improvement for chronic stroke patients.

FEATURE	INNOVATIVE NEUROTRONICS, INC. WALKAIDE Current Submission	INNOVATIVE NEUROTRONICS, INC. WALKAIDE K123972	COMPARISON
Power Source	1.5 V AA Battery (not rechargeable)	1.5 V AA Battery (not rechargeable)	Identical
Microprocessor Controlled	Yes	Yes	Identical
Indicators Unit functioning Low Battery	 Yes Yes	 Yes Yes	Identical
Patient Device Set-up and Training	Done by a clinician using a Notebook/Tablet PC	Done by a clinician using a Notebook/Tablet PC	Identical
Number of Output Modes	1	1	Identical
Channels	1	1	Identical
Output Stage Type Range/Accuracy Load	Constant Voltage (Adjustable) 0 – 110 V (±10%) 1000 Ohm load	Constant Voltage (Adjustable) 0 – 110 V (±10%) 1000 Ohm load	Identical
Max Output Current	<208 mA peak @ 500 Ohm load <121 mA peak @ 1000 Ohm load	<208 mA peak @ 500 Ohm load <121 mA peak @ 1000 Ohm load	Identical
Max Output Voltage (baseline to peak; load)	121 V 1000 Ohm load <150 V 1M Ohm load	121 V 1000 Ohm load <150 V 1M Ohm load	Identical

FEATURE	INNOVATIVE NEUROTRONICS, INC. WALKAIDE Current Submission	INNOVATIVE NEUROTRONICS, INC. WALKAIDE K123972	COMPARISON
Ramp Modulations (for gait) Ramp Up Ramp Down	 Yes Yes	 Yes Yes	Identical
Waveform Monophasic or Biphasic Symmetrical or Asymmetrical Shape	 Biphasic Asymmetrical	 Biphasic Asymmetrical	Identical
Pulse Duration	25-300 microseconds. Accuracy ±5% or ±7 microseconds, whichever is greater.	25-300 microseconds. Accuracy ±5% or ±7 microseconds, whichever is greater.	Identical
Frequency Range (Pulses per second)	16.7 to 33.3 (Adjustable) pps	16.7 to 33.3 (Adjustable) pps	Identical
Stimulation Trigger Source (When used for gait)	Tilt Sensor or Foot Sensor	Tilt Sensor or Foot Sensor	Identical
Burst Duration Stimulation when used for gait Max. Burst Duration (Seconds)	Dependent on length and speed of stride 5	Dependent on length and speed of stride 5	Identical
Max Phase Charge: 500 Ohms: 1K Ohms:	 50 microCoulombs 30 microCoulombs	50 microCoulombs 30 microCoulombs	Identical
Max. Current Density	25.3 mA/cm^2, peak	25.3 mA/cm^2, peak	Identical

FEATURE	INNOVATIVE NEUROTRONICS, INC. WALKAIDE Current Submission	INNOVATIVE NEUROTRONICS, INC. WALKAIDE K123972	COMPARISON
Maximum Average Current Density	0.25 mA/cm^2, avg.	0.25 mA/cm^2, avg.	Identical
Max. Average Power Densit	27.6 mW/cm^2 (Using 500 Ohm)	27.6 mW/cm^2 (Using 500 Ohm)	Identical
Electrode Size and Shape (Smallest recommended)	3.175 cm (1.25 inches) diameter Round	3.175 cm (1.25 inches) diameter Round	Identical
Electrode material (Basic mechanical element) Material contacting skin	Hydrogel and Stainless Steel (SS) 316	Hydrogel and Stainless Steel (SS) 316	Identical
Housing Material	ABS	ABS	Identical

Non-clinical performance testing summary:

17-11
IEC 60601-2-10
Edition 2.0 2012-06, medical electrical equipment -- part 2-10: particular requirements for the basic safety and essential performance of nerve and muscle stimulators. (Neurology)

*1*9-1

IEC 60601-1-2
Edition 3: 2007-03, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests. (General II (ES/EMC))

19-4

AAMI / ANSI
ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic safety and essential performance (iec 60601-1:2005, mod). (General II (ES/EMC))

7. CONCLUSIONS

As indicated in the comparison table above the device and software are identical to the predicate K123972. The only change is in the indications for use, and clinical data has been presented for this.

The results of this study show the WA to be equivalent to the AFO for improvements in gait velocity, SIS composite score and safety. The WA produces physiological dorsiflexion, with all the motor and sensory benefits inherent in active muscle contraction, including improved gait speed and improved overall quality of gait for individuals poststroke. Results from this study support the fact that use of the WA produces clinically relevant improvement in functional ambulation and thus should be considered a viable alternative to conventional bracing for individuals with foot drop secondary to chronic stroke. Because these results were reported in a population of individuals averaging 6.9 years from onset of stroke, this study demonstrates that functional improvements can be obtained in the chronic phase of stroke with appropriate intervention, and that continued recovery of function should remain a goal throughout the lifetime of a person with stroke.